

REMARKS

1. Claims

It is clear from reading the November 6, 2006 notice to comply that the Examiner is considering the wrong claims set. A comment sheet states "claims 14-16 contain nucleic acid sequences with no sequence identifiers".

The instant application included a courtesy copy of the IPER. Section 20 of the transmittal letter stated "Annexes are attached", but are not to be used for initial examination in this case". The copy of the IPER had a cover page attached saying "Annexes are attached, but are not to be used for initial examination in this case". (Ex. A). Thus, the pending claims, as of December 27, 2004, were the claims of the international application as originally filed, and not the IPER claims.

Claims 14-16 of the original PCT claims set don't recite any sequences. We believe the Examiner mistakenly considered the IPER claims set, in which 14-16 do recite such sequences.

In the interest of expediting prosecution, we have reviewed the correct claims set (the original 37 PCT claims) and identified those which require addition of SEQ ID NOS (claims 18-20).

Hence, the instant amendment is directed to the original PCT claims, and, inter alia, adds SEQ ID NOS to claims 18-20.

2. Additional Claims Fees

The transmittal letter, page 2, plainly instructed the RO/US that we were only paying the basic filing, examination and search fees, and the application size fee, adding "At this time no authorization is given to charge any additional fees relating to extra claims, etc."

Our PTO deposit account was nonetheless charged, in June 2005, for additional claims fees, as follows:

<u>Date</u>	<u>Fee Code</u>	<u>Amt</u>
6/13	2615	\$200.00
6/13	2616	\$180.00

Fee Code 2615 is for extra total claims, and 2616 for multiple dependency. Under 37 CFR 1.26, we have two years from the date of the deposit account statement to demand refund of these fees, which were charged "by mistake or in excess of that required." On even date herewith, we filed a request for refund.

Normally, the correct procedure would be for the PTO to reverse the erroneous charges and issue a "notice to pay additional fees". However, no refund is necessary because we have also retroactively withdrawn small entity status.

However, to expedite matters (avoid wasting time for processing a notice to pay), the instant amendment eliminates multiple dependency, asks that the additional claims fees due be calculated on the basis of the amended claims, and pays the fees thus due.

### 3. Sequence Requirements

3.1. We have already addressed the PTO error concerning claims 14-16.

3.2. Another comment sheet asserts "CRF, paper copy of sequence listing, and statement that both are the same are missing". We filed these on August 12, 2005. Checking private PAIR, the response and sequence listing are in the IFW, but are not listed in the transaction history. I spoke

with Donna Greene on November 29, 2006, and she confirms they were received.

3.3. It has come to our attention that the specification does not comply with 37 CFR 1.821 et seq. in that it contains sequences not set forth in the sequence listing and/or not identified in the specification by a SEQ ID NO:. We have added SEQ ID NOs:173-216 to the Sequence Listing.

3.3.1. Applicants hereby submit the following:

an amendment to the paper copy of the "Sequence Listing" submitted on December 27, 2004, the amendment being in the form of substitute sheets;

the Sequence Listing in computer readable form, complying with §1.821(e) and §1.824, including, if an amendment to the paper copy is submitted, all previously submitted data with the amendment incorporated therein.

3.3.2. The description has been amended to comply with §1.821(d) .

3.3.3. The undersigned attorney or agent hereby states as follows:

- (a) this submission does not include new matter [§1.821(g)] ;
- (b) the contents of the paper copy (as amended, if applicable) and the computer readable form of the Sequence Listing, are the same [§1.821(f) and §1.825(b)] ;
- (c) if the paper copy has been amended, the amendment is supported by the specification and does not include new matter [§1.825(a)] ; and
- (d) if the computer readable form submitted herewith is a substitute for a form found upon receipt by the PTO to be damaged or unreadable, that the substitute data is identical to that originally filed [§1.825(d)] .

3.3.4. Under U.S. rules, each sequence must be classified in <213> as an "Artificial Sequence", a sequence of "Unknown" origin, or a sequence originating in a particular organism, identified by its scientific name.

Neither the rules nor the MPEP clarify the nature of the relationship which must exist between a listed sequence and an organism for that organism to be identified as the origin of the sequence under <213>.

Hence, counsel may choose to identify a listed sequence as associated with a particular organism even though that sequence does not occur in nature by itself in that organism (it may be, e.g., an epitopic fragment of a naturally occurring protein, or a cDNA of a naturally occurring mRNA, or even a substitution mutant of a naturally occurring sequence). Hence, the identification of an organism in <213> should not be construed as an admission that the sequence *per se* occurs in nature in said organism.

Similarly, designation of a sequence as "artificial" should not be construed as a representation that the sequence has no association with any organism. For example, a primer or probe may be designated as "artificial" even though it is necessarily complementary to some target sequence, which may occur in nature. Or an "artificial" sequence may be a substitution mutant of a natural sequence, or a chimera of two or more natural sequences, or a cDNA (i.e., intron-free sequence) corresponding to an intron-containing gene, or otherwise a fragment of a natural sequence.

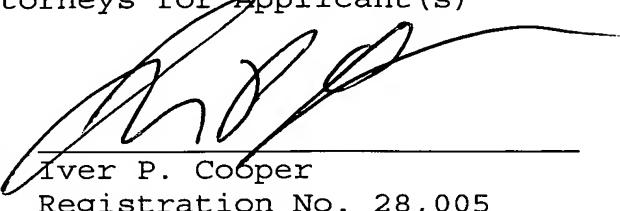
The Examiner should be able to judge the relationship of the enumerated sequences to natural sequences by giving full consideration to the specification, the art cited therein, any further art cited in an IDS, and the results of his or her

sequence search against a database containing known natural sequences.

Respectfully submitted,

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